

EXHIBIT 67

**OBSOLETE COPY**

Department Operating Instructions

TOTOWA LLC

Title:

TABLET PRESS - CLEANING

DOI #: PRD-022

Revision #: 06

Effective Date: 07/24/07

APPROVALS	Name/Title	Signature	Date
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1.0 OBJECTIVE:

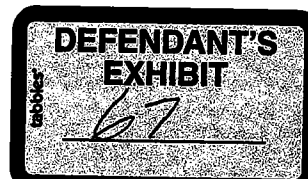
The objective of this instruction is to establish a procedure for the cleaning of tablet presses used in the manufacturing of solid dosage drug product.

2.0 SCOPE:

Procedure applies to the disassembly and cleaning of tablet presses used to manufacture solid dosage drug product at the Actavis Totowa facilities. This procedure is to be followed for "Dry" cleaning (batch to batch change over) and "Wet" cleaning (product to product changeover and matrix cleaning) of tablet presses.

3.0 RESPONSIBILITY:

- 3.1 Area Supervisors/Designees must ensure this procedure is followed when performing a "Dry" cleaning or a "Wet" cleaning of a tablet press.
- 3.2 Operators must follow this procedure when performing a "Dry" cleaning or a "Wet" cleaning of a tablet press.



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4.0 DEFINITIONS:

- 4.1 Refer to SOP 0012, "Production Department Cleaning Procedures", for definitions related to cleaning operations and safety precautions.

5.0 PROCEDURE:**5.1 "Dry" Cleaning**

- 5.1.1 Remove the product feed hopper and funnel, the force feeder, turret guard, and the product discharge chute (removable parts) from the tablet press. Vacuum any loose excess product waste and discard it into a suitable container labeled with a Reject label.
- 5.1.2 Vacuum any remaining loose excess product waste of the previous batch from all surfaces of the tablet press removable parts.
- 5.1.3 Inspect the tablet press removable parts for the presence of any damage or foreign material. Report any findings to the Area Supervisor immediately for evaluation.
- 5.1.4 Open the access panel covering the upper punches to allow access to the upper punches.
- 5.1.5 Using the turntable hand wheel, manually rotate the die table and using compressed air, blow loose excess product waste of the previous batch from the feed frame, die table, upper punches, lower punches, and other exposed parts of the tablet press.
- 5.1.6 Check the condition of each lubricant cup and report any findings to the Area Supervisor/Designee for evaluation. If there is a significant amount of lubricant in any cup, it must be cleaned with cool tap water and a nylon brush, or replaced with a clean dry cup.
Note: Do not use hot tap water or alcohol to clean the lubricant cups, as this will result in a loss of elasticity and may cause the lubricant cups to become brittle and fail during use.
- 5.1.7 Place a "CLEANED" status tag on the tablet press.
- 5.1.8 Record the completion of the cleaning process in the Equipment Usage & Cleaning Log for the specific tablet press as specified in DOI # PRD-001 and in the Room Usage and Cleaning Log as specified in DOI # PRD-002.

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5.2 "Wet" Cleaning

Note: If a "Wet" Cleaning is to be validated / verified, refer to the Tablet Press – "Wet" Cleaning Checklist (Form # F-PRD-022.A.) to document the "Wet" Cleaning. The checklist **is not** required for routine cleaning. It is required when performing a Cleaning Validation/Verification (inclusive of Routine Monitoring) or a protocol requiring the use of a checklist. The checklist is to be reviewed by the Area Supervisor or designee upon completion. Completed checklists are to be forwarded to, and maintained by, the Quality Assurance Validation department with the applicable Cleaning Validation Study.

- 5.2.1** Vacuum any loose excess product waste of the previous batch from all exterior surfaces of the tablet press.
- 5.2.2** Remove the product feed hopper and funnel, the force feeder, turret guard, and the product discharge chute (removable parts) from the tablet press. Discard any loose excess product waste into a suitable container labeled with a Reject label.
- 5.2.3** Using compressed air, blow any remaining loose excess product waste of the previous batch from all surfaces of the tablet press removable parts.
- 5.2.4** Open the access panel covering the upper punches to allow access to the upper punches.
- 5.2.5** Using the turntable hand wheel, manually rotate the die table and, using compressed air, blow loose excess product waste of the previous batch from feed frame, die table, upper punches, lower punches, and other exposed parts of the tablet press.
- 5.2.6** Carefully remove the upper punches one at a time, and remove the lubricant cup from each upper punch. Remove loose lubricant / residual product waste crust from each lubricant cup and stack the lubricant cups together and secure together with a wire tie.
- 5.2.7** Wipe each upper punch with a clean dry cloth to remove excess lubricant and residual product waste and carefully place in a clean tray.
- 5.2.8** Carefully remove the lower punches one at a time.
- 5.2.9** Wipe each lower punch with a clean dry cloth to remove excess lubricant and residual product waste and carefully place in the tray with the upper punches.

Note: In order to prevent damaging the punches, take precautions to assure that the punch tips do not hit any hard surfaces.

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- 5.2.10** For each die, remove the die screw and collect all die screws in a container. Remove each die by tapping it from the bottom and pushing it up and out of the die table. Place the dies on the tray with the punches.
- 5.2.11** Apply ZEP X13484 directly to the lower punch rail, the lower punch bores, the die table, the die bores, the upper punch rail, and the upper punch bores.
- 5.2.12** Transport the press and all removable parts to the wash area.
- 5.2.13** Cover the power switch and the end of the power cord with plastic bags to protect from moisture.
- 5.2.14** Thoroughly rinse the gears below the lower punch rail, the lower punch rail, the lower punch bores, the die table, the die bores, the upper punch rail, the upper punch bores, and the feed frame by spraying with hot tap water from a hose to remove excess product waste of the previous batch and excess lubricant.
- Note: Keep the access panel covering the top punches closed while rinsing to keep excess water out of the top of the press.
- 5.2.15** Using compressed air, blow excess water from all surfaces of the press including the gears below the lower punch rail, the lower punch rail, the lower punch bores, the die table, the die bores, the upper punch rail, the upper punch bores, the feed frame, and all other exposed surfaces of the press. Wipe these surfaces with a clean dry cloth to remove any remaining water.
- 5.2.16** Apply ZEP X13484 directly to the lower punch rail, the lower punch bores, the die table, the die bores, the upper punch rail, and the upper punch bores.
- 5.2.17** Insert a nylon bristled bottle brush into the upper punch bore and force the brush down through the upper punch bore, the die bore, and the lower punch bore three times for each station of the press. Remove excess ZEP X13484 from the lower punch rail, the lower punch bores, the die table, the die bores, the upper punch rail, and the upper punch bores with a clean dry cloth.
- 5.2.18** Wipe all exterior surfaces of the press with a clean cloth moistened with ZEP X13484.
- 5.2.19** Remove the plastic bags covering the power switch and the end of the power cord.

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- 5.2.20** Sanitize the lower punch rail, the lower punch bores, the die table, the die bores, the upper punch rail, the upper punch bores, and the feed frame by thoroughly spraying these surfaces with 70% Isopropyl Alcohol and wiping with a clean dry cloth to remove excess alcohol. Inspect these surfaces to ensure that no visible residual product waste of the previous batch remains. Repeat the cleaning procedure if necessary.
- 5.2.21** Place the upper punches, the lower punches, and the dies in the Handi-Kleen PL 36 parts washer basin. Turn the parts washer on to start the recirculation of ZEP X13484. Using the spray spout, saturate all surfaces of the punches and dies with ZEP X13484.
- 5.2.22** Remove each punch from the parts washer and wipe all surfaces of the punch with a clean dry cloth to remove excess ZEP X13484.
- 5.2.23** Remove each die from the parts washer and wipe all surfaces of each die, including the die cavity, with a clean dry cloth to remove excess ZEP X13484.
- 5.2.24** Obtain a clean dry container and fill with 25% solution of Fuller Brush Company Component 939 (Refer to DOI # PRD-095). Place the upper punches, the lower punches, the dies, and the die screws into the container of the cleaning solution, ensuring that all surfaces are submerged in the cleaning solution, and soak these parts for a minimum of 1 minute.
- 5.2.25** Remove each of the upper punches, lower punches, dies, and die screws from the cleaning solution and scrub all surfaces of each item, using a clean cloth saturated with a 25% solution of Fuller Brush Company Component 939 and cold tap water, for a minimum of 10 minutes.
- 5.2.26** Thoroughly rinse each upper punch, lower punch, die, and die screw by spraying all surfaces of each item with hot tap water from a hose for at least 5 minutes. Ensure that all visible traces of cleaning solution have been removed.
- 5.2.27** Using compressed air, blow excess water from all surfaces of the upper punches, lower punches, dies, and die screws. Dry these surfaces with a clean dry cloth to remove any remaining water.
- 5.2.28** Sanitize the upper punches, lower punches, and dies by thoroughly spraying all surfaces with 70% Isopropyl Alcohol (IPA) and dry with a clean dry cloth. Inspect these surfaces to ensure that no visible residual product waste of the previous batch remains. Repeat the cleaning procedure if necessary.

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5.2.29 Carefully place the cleaned punches and dies in their respective boxes and return them to the tool room.

5.2.30 Dip the lubricant cups into the 25% solution of Fuller Brush Company Component 939 and agitate by hand for a minimum of 1 minute.

5.2.31 After agitating for a minimum of 1 minute, remove the lubricant cups from the Fuller Brush Company Component 939 cleaning solution and thoroughly rinse each cup by spraying all surfaces with cool tap water from a hose for at least 1 minute. Ensure that all visible traces of cleaning solution have been removed.

Note: Do not use hot tap water or alcohol to clean the lubricant cups, as this will result in a loss of elasticity and may cause the lubricant cups to become brittle and fail during use.

5.2.32 Using compressed air, blow excess water from the lubricant cups and allow to air dry. Inspect these surfaces to ensure that no visible residual product waste of the previous batch remains. Repeat the cleaning procedure if necessary.

5.2.33 To remove excess product waste of the previous batch, thoroughly rinse all tablet press removable parts (including the product feed hopper and funnel, the force feeder, turret guard, the product discharge chute, die screws, and any other removable parts of the press) by spraying all surfaces with hot tap water from a hose for a minimum of 5 minutes.

5.2.34 Apply a 25% solution of Fuller Brush Company Component 939 and cold tap water to all surfaces of each tablet press removable part using a clean cloth saturated with the cleaning solution. Allow the surfaces to soak in the cleaning solution for a minimum of 1 minute.

5.2.35 Scrub all surfaces of the tablet press removable parts using a clean cloth saturated with a 25% solution of Fuller Brush Company Component 939 and cold tap water for a minimum of 10 minutes.

5.2.36 Thoroughly rinse the tablet press removable parts by spraying all surfaces with hot tap water from a hose for a minimum of 5 minutes. Ensure that all visible traces of cleaning solution have been removed.

5.2.37 Using compressed air, blow excess water from all surfaces of the tablet press removable parts. Dry these surfaces with a clean dry cloth to remove any remaining water.

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- 5.2.38** Sanitize the removable parts by thoroughly spraying all surfaces with 70% Isopropyl Alcohol (IPA) and dry with a clean dry cloth. Inspect these surfaces to ensure that no visible residual product waste of the previous batch remains. Repeat the cleaning procedure if necessary.
- 5.2.39** Discard all used cleaning cloth(s) in the appropriate trash container(s).
- 5.2.40** Cover the tablet press and its parts with clean plastic sheets.
- 5.2.41** Place a "CLEANED" status tag on the tablet press.
- 5.2.42** Record the completion of the cleaning process in the Equipment Usage & Cleaning Log for the specific tablet press as specified in DOI # PRD-001 and the Room Usage and Cleaning Log as specified in DOI # PRD-002.

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DOCUMENT HISTORY FORM:

REV. NO	EFFECTIVE DATE	REASON FOR REVISION
00		Initial
05		Added Scope to DOI. Added new step 2 for lockout/tagout. Reworded text for clarity. Added new company name to header. Step 11: added approved cleaning agent to reflect current practice.
06		Modified cleaning procedure to reflect current practices for Dry cleaning and Wet cleaning. Reformatted text to new DOI outline. Added reference to the Cleaning Validation Checklist Form.

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